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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/743,762	05/14/2001	Cecilia Larsson	1547/00275	7301

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EXAMINER

MATTHEWS, WILLIAM H

ART UNIT	PAPER NUMBER
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3738

DATE MAILED: 09/12/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/743,762

Applicant(s)

LARSSON ET AL.

Examiner

William H. Matthews (Howie)

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 12 September 2001.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 31-53 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 31-53 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☒ All b) ☐ Some \* c) ☐ None of:  
1. ☒ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6. 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Specification***

1. The specification is objected to because of references listed in the specification and not in an information disclosure statement. All references listed in the specification should be included in an information disclosure statement. Correction is required. See MPEP § 608.01(b).

### ***Claim Objections***

2. Claims 45-50 are objected to because of the following informalities: claims 45-50 depend upon a cancelled claim. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 31-44 and 51-53 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Lines 6-8 of claim 31 are unclear as to what is positively claimed for the preparation. The phrase "and/or lipid type" on line 8 is indefinite. Furthermore, the phrase "for instance" in line 3 is indefinite, the use of repetitive "or" statements renders the scope of the claim unclear, and in lines 6-7, use of "preparation" in two ways is unclear, and finally in line 9, the phrase "such as bodily fluid" is indefinite.

Claims 44 and 52 are indefinite because of the recitation "it" in line 1 of each claim. "It" should be replaced with the element that "it" refers to.

Claims 32-43, 51, and 53 are rejected for being dependent upon a rejected base claim.

***Claim Rejections - 35 USC § 102***

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

6. Claims 31,36,38,40,45-48, and 50 are rejected under 35 U.S.C. 102(b) as being anticipated by NGK Spark Plug Co Ltd (JP 2198560).

See abstract.

7. Claims 31,39-42,45-47, and 51 are rejected under 35 U.S.C. 102(b) as being anticipated by Larsson et al. (US PN 5,196,201).

Larsson et al. discloses a preparation for restoring bone utilizing calcium phosphate or tricalcium phosphate, vegetable oil, and a water based liquid. See entire document.

8. Claims 31,45-47, and 49-53 rejected under 35 U.S.C. 102(b) as being anticipated by Bauer et al. (US PN 5,338,772).

Bauer et al. discloses a preparation for restoring bone utilizing calcium phosphate or tricalcium phosphate having a porosity up to 90% and particle sizes of up to about 3mm, and being mixed with natural fats (see columns 3-4). Furthermore, growth factors are disclosed in lines 37-53 of column 7.

\* 9. Claims 31,43,44,52, and 53 are rejected under 35 U.S.C. 102(e) as being anticipated by Cassidy et al. (US PN 6,280,474).

Cassidy et al. discloses a preparation for restoring bone having a bioabsorbable polymer containing sodium hyaluronic acid and calcium phosphate granules as well as growth factors. See columns 11-12.

### ***Claim Rejections - 35 USC § 103***

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. Claims 32-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bauer et al. US PN 5,338,772 in view of Haynes et al. US PN 5,972,366.

Bauer et al. meets the limitations of claims 32-38 as described above in paragraph 8, but lacks the express disclosure of phospholipids and esterified glycerol. Bauer et al. discloses the use of natural fats that are composed of esterified glycerol and possibly phospholipids. However, in the event that natural fats lack phospholipids, Haynes et al. teaches a device for implantation in bone to stimulate healing and bone growth comprising a drug (col. 5) releasing medium consisting of phospholipids and more specifically sphingomyeline and phosphatidyl choline (col. 7) in order to release bone growth drugs over an extended period of time and prevent the drug from migrating away from the drug's target area.

Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have included the specific phospholipids taught by Haynes et al. '366 in the preparation disclosed by Bauer et al. in order to release bone growth drugs over extended period of time and prevent the drug from migrating away from the drug's target area.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to William H. Matthews (Howie) whose telephone number is 703-305-0316. The examiner can normally be reached on Mon-Fri 7:00-4:30 (Every other Friday off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine M. McDermott can be reached on 703-308-2111. The fax phone

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numbers for the organization where this application or proceeding is assigned are (703) 308-2708 for regular communications and (703) 305-3590 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.



WHM

September 5, 2002



**Paul B. Preblich**  
**Primary Examiner**